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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/129,603	08/05/1998	TETSUYOSHI ISHIWATA	766-25	4777

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FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER
LACOURCIERE, KAREN A

ART UNIT	PAPER NUMBER
1635	21

DATE MAILED: 12/04/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/129,603	ISHIWATA ET AL.	
	Examiner	Art Unit	
	Karen A. Lacourciere	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-7,10 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,5-7,10 and 11* is/are rejected.

7)☒ Claim(s) *3 and 4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

WILLIAM N. PHILLIPS
PATENT ANALYST

wp

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 2-7 10 and 11 are pending in the instant application.

Claim Objections

2. Claim 10 is maintained as objected to because of the following informalities: in line 3 of claim 10 there is no article before the phrase "15 mer portion". This objection would be obviated by insertion of the word "a" before the phrase "15 mer portion" in line 3 of the claim. Claim 10 is further objected to because the word "oligonucleotides" is misspelt as "oligonuleotides" in the 15th line of the claim. Claim 10 is further objected to because the word "nephropathy" appears to be missing after the word "IgA" in the 18th line of the claim. Claim 10 is further objected to because the last line of the claim recites "reverse-transcription claim reaction", when it should recite "reverse-transcription chain reaction". Appropriate correction is required.

Claims 3 and 4 are objected to due to their dependence on a rejected claim (claim 2), but would be allowable if rewritten to be independent of the rejected claim.

Claim Rejections - 35 USC § 101

The rejection of record of claim 2 under 35 U.S.C. 101, as set forth in the prior Office action (mailed 03-14-01), is withdrawn in response to Applicant's amendments, filed 09-20-01.

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claim 7 is maintained as rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility, for the reasons of record set forth in the prior Office action (mailed 03-14-01). The rejection of record is repeated as follows.

Claim 7 is drawn to a process of producing a protein comprising an amino acid sequence of SEQ ID NO:2. This process is not supported by either a specific and/or substantial utility or a well established utility because it is a method of making a protein which does not have either a specific and/or substantial utility or well established utility.

The specification discloses a polynucleotide (SEQ ID NO:1) which is upregulated in leukocytes of patients with an IgA nephropathy. SEQ ID NO:2 is the sequence of a polypeptide which has been translated from one possible open reading frame of SEQ ID NO:1. The specification does not demonstrate that SEQ ID NO:2 is a translation of the open reading frame of SEQ ID NO:1 expressed in human cells, it does not demonstrate that SEQ ID NO:2 or any other polypeptide is overexpressed in cells of IgA nephropathy patients, nor does it provide any other function of a polypeptide of SEQ ID NO:2. The specification asserts that a polypeptide of SEQ ID NO:2 can be utilized to make an antibody to SEQ ID NO:2 and that said antibody can be used to detect expression of a polypeptide of SEQ ID NO:2 and can be used as a diagnostic or a

therapeutic agent. This is a non-specific use that is applicable proteins in general and not particular or specific to the protein being claimed. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case the antibodies that are to be produced as final products using a protein of SEQ ID NO:2 do not have specific and substantial utilities. SEQ ID NO:1 has utility based on the demonstration that SEQ ID NO:1 is selectively upregulated in leukocytes of IgA nephropathy patients; however, there is no indication that SEQ ID NO:1 expresses a protein of SEQ ID NO:2 or that a protein of SEQ ID NO:2 is expressed in IgA nephropathy patient's cells at a level higher than that of a normal patient's cells. As such, neither an antibody produced using SEQ ID NO:2 nor a protein of SEQ ID NO:2 would have utility for diagnostic methods or therapeutics for an IgA nephropathy. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the a protein of SEQ ID NO:2 such that another non-asserted utility would be well established for the compounds. Therefore, a process for producing a polypeptide of SEQ ID NO:2 is not supported by either a specific and/or substantial utility or a well established utility.

Claim Rejections - 35 USC § 112

5. The rejection of record of claims 10 and 11 under 35 U.S.C. 112, second paragraph, set forth in the prior Office action (mailed 03-14-01) is withdrawn in response to Applicant's amendments and arguments filed 09-20-01.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 7 is also maintained as rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record set forth in the prior Office action (mailed 03-14-01). Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

8. Claims 2, 5, 6, 10 and 11 are maintained as rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions of a nucleic acid comprising SEQ ID NO:1 or sequences which hybridize to SEQ ID NO:1 and diagnostic methods using said nucleic acids, does not reasonably provide enablement for compositions comprising a nucleic acid which encodes a polypeptide of SEQ ID NO:2 or sequences which hybridize to a nucleic acid which encodes a polypeptide of SEQ ID NO:2 and diagnostic methods using said nucleic acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the prior Office action (mailed 03-14-01). The rejection of record is repeated as follows.

The following factors have been considered in formulating this rejection (*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)): the breadth of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

Claims 2, 5, 6, 10 and 11 are drawn to nucleic acids which encode a polypeptide of SEQ ID NO:2, a nucleic acid of SEQ ID NO:1, nucleic acids which hybridize to SEQ ID NO:1, vectors and host cells comprising such and diagnostic methods for detecting an IgA nephropathy using a 15 mer portion of a nucleic acid which encodes a polypeptide of SEQ ID NO:2, a nucleic acid of SEQ ID NO:1, or a nucleic acid which hybridizes to SEQ ID NO:1.

The specification demonstrates that elevated levels of mRNA of SEQ ID NO:1 can be selectively detected in leukocytes from IgA nephropathy patients. The specification does not demonstrate that SEQ ID NO:1 expresses a polypeptide of SEQ ID NO:2 in IgA nephropathy patients, nor that any nucleic acid expressing a polypeptide of SEQ ID NO:2, besides SEQ ID NO:1, is expressed in cells of an IgA nephropathy patient at an abnormal level, or even if a nucleic acid encoding SEQ ID NO:2 (besides SEQ ID NO:1) is even expressed in any cells. Although the specification correlates overexpression of an mRNA of SEQ ID NO:1 with an IgA nephropathy, there is no correlation between a polypeptide of SEQ ID NO:2 and an IgA nephropathy. There is no evidence that a polypeptide of SEQ ID NO:2 is ever expressed in cells, nor that generally any nucleic acid encoding a polypeptide of SEQ ID NO:2 correlates with an IgA nephropathy or any

other disorder. To determine whether any mRNA encoding a polypeptide of SEQ ID NO:2 (besides SEQ ID NO:1) is expressed in tissues and, if expressed, whether or not the expression level of said mRNA correlates with an IgA nephropathy, one skilled in the art would need to undergo undue trial and error experimentation, beyond the teachings of the instant specification.

Response to Arguments

9. Applicant's arguments filed 09-20-01 have been fully considered but they are not persuasive.

In response to the rejection of record of claims 2, 5-7, 10 and 11, Applicant argues that the asserted utility of SEQ ID NO:2 is substantial (ie. use to make antibodies for use in assays), and, therefore, it is irrelevant. Further, Applicant argues that the asserted utility is specific, that is the amino acid of SEQ ID NO:2 would be considered by those of ordinary skill in the art to be encoded by the mRNA of SEQ ID NO:1. Applicant argues that SEQ ID NO:2 is the longest ORF in SEQ ID NO:1 and that SEQ ID NO:2 has homology with proteins known in the art to have RNA binding capabilities and, therefore, is not a meaningless protein. Applicant states that declarations supporting these assertion could be provided, however, no declarations have been provided. Applicant argues that since one of ordinary skill in the art would expect SEQ ID NO:2 to be encoded by SEQ ID NO:1 and SEQ ID NO:1 mRNA is increased in leukocytes in IgA nephropathy patients that the protein of SEQ ID NO:2 would also be increased.

These arguments have not been found to be persuasive. the rejection of record sets forth a lack of utility for a method of producing a protein of SEQ ID NO:2, use a that protein to make antibodies to a protein which lacks utility is in itself not a utility. An antibody generated to a protein of SEQ ID NO:2 would not have utility in an assay to detect a protein of SEQ ID NO:2, because SEQ ID NO:2 has no utility, as discussed in the record of rejection under 35 U.S.C. 101, because there is no correlation between the expression of a protein of SEQ ID NO:2 and an IgA nephropathy, or any other disorder. Applicant's arguments that SEQ ID NO:2 is expressed is an unsupported assertion. Further, the homology cited by Applicant between SEQ ID NO:2 and the C terminal portion of an RNA binding protein does not provide any correlation between SEQ ID NO:2 and an IgA nephropathy. Further, a possible RNA binding activity of SEQ ID NO:2 would not constitute a substantial and specific utility for a protein encoded by SEQ ID NO:2.

Conclusion

Any rejection of record not repeated herein is considered to be withdrawn.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Karen A. Lacourciere at telephone number (703)308-7523. The examiner can normally be reached 8:30 am to 6:30 pm, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached at (703) 308-0447. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Karen A. Lacourciere
November 29, 2001